

General

Title

Implantable cardioverter-defibrillator (ICD): risk-standardized rate of procedural complications following the first time implantation of an ICD.

Source(s)

Heart Rhythm Society (HRS). HRS-3 implantable cardioverter-defibrillator (ICD) complications rate. Washington (DC): Heart Rhythm Society (HRS); 2015 Dec 18. 12 p.

Measure Domain

Primary Measure Domain

Clinical Quality Measures: Outcome

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure is used to assess the physician-specific risk-standardized rate of procedural complications following the first time implantation of an implantable cardioverter-defibrillator (ICD).

This measure is to be reported a minimum of once per reporting period for patients with a first time implantation of an ICD during the reporting period. This measure may be reported by clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

There are two reporting criteria for this measure:

- Patients with first time implants with one or more complications or mortality within 30 days
- Patients with first time implants with one or more complications within 90 days

Rationale

The proposed measure of implantable cardioverter-defibrillator (ICD) complications has the potential to significantly improve the quality of care delivered to patients with advanced heart disease. The model used for risk adjustment meets recognized standards for outcomes measurement and was developed with extensive input from stakeholders with a broad range of expertise and perspectives. The study sample is appropriately defined, consisting of an ICD population that has distinct outcomes that will allow for valid comparisons of physician quality. The definition of the complications, the complication-specific period of assessment, and the risk-adjustment variables all have strong face validity, which may facilitate physician acceptance. The developer excluded covariates that it would not want to adjust for in a quality measure.

In summary, the developer presents an ICD complications measure that is suitable for public reporting. The proposed measure capitalizes on the National Cardiovascular Data Registry (NCDR) ICD Registry data already collected as part of an ongoing collaboration between Centers for Medicare & Medicaid Services (CMS) and NCDR. Accordingly, the incremental burden of data collection on physicians would be minimal and the proposed measure could be implemented by using the direct patient identifiers already being collected by CMS.

ICD implantation is an expensive procedure performed on patients with advanced cardiovascular disease and, often, significant comorbidities. Despite improvements in technology and increasing experience with device implantation, the procedure carries a significant risk of complications (Hammill & Curtis, 2008).

Roughly 150,000 ICDs are implanted each year and approximately two thirds of implantations are performed on Medicare patients.

Direct total medical cost per device (Sanders, Hlatky, & Owens, 2005) is \$68,000 to \$100,000. The total national costs range from \$10 to \$15 billion, of which \$7 to \$10 billion represents fee-for-service (FFS) Medicare.

Complications are expensive and, in one study (Reynolds et al., 2006), associated with increased length of stay (1 to 10 days) and costs \$5,000 to 20,000 (mean \$7,251), adding roughly \$80 million in Medicare costs.

Reported complication rates following ICD implantation vary from 4% to 30%, depending largely on how complications are defined and the period of assessment. In the NCDR ICD Registry, the incidence of in-hospital complications is approximately 4%. However, complications such as device infection, malfunction, or cardiac tamponade are not fully captured by the registry since they may only become evident following hospital discharge.

Al-Khatib et al. (2008) analyzed administrative claims data and found overall rates of complication within 90 days of ICD implantation ranged from 18.8% in 2002 to 14.2% in 2005 (Al-Khatib et al., 2005).

The developer analyzed Medicare FFS administrative claims to assess complications rates following ICD implantation. From 2006 through 2009, a total of 105,575 implants performed by 3,488 physicians met inclusion/exclusion criteria and were included in the analysis. The number of eligible implants increased over time from 22,931 in 2006 to 28,383. The overall complication rate decreased modestly over this time period, from 8.60% to 7.55%. The rate of mechanical complications requiring system revision had the largest decrease over time (0.78%), but similar relative declines were seen across all complications. As expected, the characteristics of patients with and without adverse events differed significantly. Most notably, patients receiving a cardiac resynchronization therapy (CRT-D) device had a significantly higher complication rate than patients receiving a single and dual chamber device (8.09%, 6.30%, and 5.33% respectively). These results demonstrate an opportunity to improve physician-level performance.

Evidence for Rationale

Al-Khatib SM, Greiner MA, Peterson ED, Hernandez AF, Schulman KA, Curtis LH. Patient and implanting physician factors associated with mortality and complications after implantable cardioverter-defibrillator implantation, 2002-2005. *Circ Arrhythm Electrophysiol*. 2008 Oct;1(4):240-9. [PubMed](#)

Al-Khatib SM, Lucas FL, Jollis JG, Malenka DJ, Wennberg DE. The relation between patients' outcomes and the volume of cardioverter-defibrillator implantation procedures performed by physicians treating Medicare beneficiaries. J Am Coll Cardiol. 2005 Oct 18;46(8):1536-40. [PubMed](#)

Hammill SC, Curtis J. Publicly reporting implantable cardioverter defibrillator outcomes: grading the report card. Circ Arrhythm Electrophysiol. 2008 Oct;1(4):235-7. [PubMed](#)

Heart Rhythm Society (HRS). HRS-3 implantable cardioverter-defibrillator (ICD) complications rate. Washington (DC): Heart Rhythm Society (HRS); 2015 Dec 18. 12 p.

Reynolds MR, Cohen DJ, Kugelmass AD, Brown PP, Becker ER, Culler SD, Simon AW. Complications among Medicare beneficiaries, receiving implantable cardioverter-defibrillators. J Am Coll Cardiol. 2006 Jun 20;47(12):2493-7. [PubMed](#)

Sanders GD, Hlatky MA, Owens DK. Cost-effectiveness of implantable cardioverter-defibrillators. N Engl J Med. 2005 Oct 6;353(14):1471-80. [PubMed](#)

Primary Health Components

Implantable cardioverter-defibrillator (ICD) implantation; procedural complications; mortality

Denominator Description

Patients with a first time implantation of an implantable cardioverter-defibrillator (ICD) (see the related "Denominator Inclusions/Exclusions" field)

Numerator Description

Reporting Criteria 1: Number of patients with one or more of the specified complications or mortality within 30 days (depending on the complication) following implantable cardioverter-defibrillator (ICD) implantation

Reporting Criteria 2: Number of patients with one or more of the specified complications within 90 days (depending on the complication) following ICD implantation

See the related "Numerator Inclusions/Exclusions" field.

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A formal consensus procedure, involving experts in relevant clinical, methodological, public health and organizational sciences

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Additional Information Supporting Need for the Measure

Unspecified

Extent of Measure Testing

In March 2010, the Heart Rhythm Society's (HRS) Quality Improvement Subcommittee conducted a strategic planning meeting to identify recommendations on how the Society could best prepare for the increased focus of performance measurement by the United States (U.S.) government and others. The topics discussed included performance measurement in general, as well as public reporting and value-based purchasing, specifically. Through the work of the Measure Development Task Force during Cycle 1 of the initiative, two physician-level measures were fully-specified and tested: *HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate* and *HRS-4: In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED)*. The measures were developed with the intent to submit them to the National Quality Forum (NQF) for endorsement consideration when a relevant call for measures is issued. Pilot testing is a prerequisite for NQF.

Evidence for Extent of Measure Testing

Heart Rhythm Society (HRS). Performance measure development initiative quality improvement pilot implementation plan. Washington (DC): Heart Rhythm Society (HRS); 9 p.

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Hospital Inpatient

Hospital Outpatient

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Individual Clinicians or Public Health Professionals

Statement of Acceptable Minimum Sample Size

Does not apply to this measure

Target Population Age

Age greater than or equal to 65 years

Target Population Gender

Either male or female

National Strategy for Quality Improvement in Health Care

National Quality Strategy Aim

Better Care

National Quality Strategy Priority

Making Care Safer

Prevention and Treatment of Leading Causes of Mortality

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Safety

Data Collection for the Measure

Case Finding Period

- *Reporting Criteria 1*: January 1 through November 30
- *Reporting Criteria 2*: January 1 through September 30

Denominator Sampling Frame

Patients associated with provider

Denominator (Index) Event or Characteristic

Encounter

Institutionalization

Patient/Individual (Consumer) Characteristic

Therapeutic Intervention

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions

Patients with a first time implantation of an implantable cardioverter-defibrillator (ICD)

Reporting Criteria 1: Include patients with procedures that are performed greater than or equal to 31 days prior to the end of the reporting period.

Reporting Criteria 2: Include patients with procedures that are performed greater than or equal to 91 days prior to the end of the reporting period.

Denominator Criteria (Eligible Cases):

Patient aged greater than or equal to 65 years on date of encounter

AND

Implantation of ICD (refer to the original measure documentation for International Classification of Diseases, Tenth Revision, Procedure Coding System [ICD-10-PCS] codes)

AND/OR

Patient encounter during reporting period (refer to the original measure documentation for Current Procedural Terminology [CPT] codes)

AND NOT

ICD-10-PCS codes: 0JPT0PZ, 0JPT3PZ

Note: Include only patients that have had first time implantation through November 30 for evaluation of complications for 30 days and September 30 for evaluation of complications for 90 days post procedure within the reporting period. This will allow the evaluation of ICD implant complications within the reporting year.

Exclusions

None

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions

Reporting Criteria 1: Number of patients with one or more of the following complications or mortality within 30 days (depending on the complication) following implantable cardioverter-defibrillator (ICD) implantation

Complications measured for 30 days:

- Death
- Pneumothorax or hemothorax plus a chest tube
- Hematoma plus a blood transfusion or evacuation
- Cardiac tamponade or pericardiocentesis

Reporting Criteria 2: Number of patients with one or more of the following complications within 90 days (depending on the complication) following ICD implantation

Complications measured for 90 days:

- Mechanical complications requiring a system revision
- Device related infection
- Additional ICD implantation

Note:

The eligible professional should submit data on both Reporting Criteria 1 and 2 for a patient that meets the denominator. Refer to the original measure documentation for administrative codes.

Exclusions

None

Numerator Search Strategy

Fixed time period or point in time

Data Source

Administrative clinical data

Registry data

Type of Health State

Adverse Health State

Instruments Used and/or Associated with the Measure

- 2016 Registry Individual Measure Flow: PQRS #348 HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate–Reporting Criteria One
- 2016 Registry Individual Measure Flow: PQRS #348 HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate–Reporting Criteria Two

Computation of the Measure

Measure Specifies Disaggregation

Measure is disaggregated into categories based on different definitions of the denominator and/or numerator

Basis for Disaggregation

There are two reporting criteria for this measure:

Reporting Criteria 1: Patients with first time implants with one or more complications or mortality within 30 days.

Denominator: Patients with a first time implantation of an implantable cardioverter-defibrillator (ICD)

Numerator: Number of patients with one or more of the following complications or mortality within 30 days (depending on the complication) following ICD implantation

Reporting Criteria 2: Patients with first time implants with one or more complications within 90 days.

Denominator: Patients with a first time implantation of an ICD

Numerator: Number of patients with one or more of the following complications within 90 days (depending on the complication) following ICD implantation

Scoring

Rate/Proportion

Interpretation of Score

Desired value is a lower score

Allowance for Patient or Population Factors

not defined yet

Description of Allowance for Patient or Population Factors

Hierarchical Logistic Regression

The specification is designed to align with the National Quality Forum (NQF)-endorsed *Hospital Risk-Standardized Complication Rate following Implantation of Implantable Cardioverter-Defibrillator* performance measure (NQF #0694).

The variables apply to both the 30 and 90 day outcomes, but how the variables are to be utilized within the performance calculation is part of a risk model developed by Yale.

Standard of Comparison

not defined yet

Identifying Information

Original Title

HRS-3: implantable cardioverter-defibrillator (ICD) complications rate.

Submitter

Heart Rhythm Society - Disease Specific Society

Developer

Heart Rhythm Society - Disease Specific Society

Funding Source(s)

Unspecified

Composition of the Group that Developed the Measure

The Heart Rhythm Society Performance Measures Development Task Force consists of thought leaders in atrial fibrillation ablation, device implantation, cardiovascular health policy, performance measures development, patient safety, clinical outcomes, and population science. The roster can be provided upon request at policy@hrsonline.org.

Financial Disclosures/Other Potential Conflicts of Interest

Conflicts, if any, are disclosed in accordance with the Heart Rhythm Society conflict of interest disclosure policy.

Measure Initiative(s)

Physician Quality Reporting System

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2015 Dec

Measure Maintenance

Unspecified

Date of Next Anticipated Revision

Unspecified

Measure Status

This is the current release of the measure.

This measure updates a previous version: Heart Rhythm Society. Performance measure technical specifications. Washington (DC): Heart Rhythm Society; 2014 Sep. 5 p.

Measure Availability

Source not available electronically.

For more information, contact the Heart Rhythm Society (HRS) at 1325 G Street, NW, Suite 400, Washington, DC 20005; Phone: 202-464-3400; Fax: 202-464-3401; E-mail: info@HRSonline.org; Web site: www.hrsonline.org .

NQMC Status

This NQMC summary was completed by ECRI Institute on January 26, 2015. The information was verified by the measure developer on February 23, 2015.

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Production

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